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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,570	03/22/2004	Steven J. Smith	3472-4001US1	2210

7590 05/31/2006

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,570	SMITH, STEVEN J.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the continuation-in-part, received 3/22/04.

Claims 1-39 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

Nature of the invention.

The claimed invention is drawn to a method for selecting a patient for p53-specific therapy, wherein the p53-selective therapy is genetic therapy with p53-encoding DNA.

State of the prior art.

As recently as May 17, 1996, the American Society of Clinical Oncology summarized the current-state-of-the-art in the use of tumor marker tests in prevention, screening, treatment and surveillance of breast and colorectal cancers. It assessed a variety of tumor markers, such as p53. The consensus report concluded that such markers continued to have limited prognostic or predictive value. When DNA mutations are assessed, it is often not clear which mutations have an impact upon gene function (see, i.e., instant specification, page 6, lines 9-15)

Working examples.

No working example is disclosed in the specification.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 39 recite, "...in a hydrophilic matrix". The claim is indefinite because the metes and bounds of what is encompassed within the definition of a hydrophilic matrix are not set forth in the disclosure.

Claim 1 recites, "... without substantial intervening fixation...". The term "substantial" renders the claim vague and indefinite because the specification fails to define what is encompassed; i.e. how much fixation is "substantial".

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC 112, second paragraph.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,4-18, and 39 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,746,848. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method of preparing calibration slides for cell imaging densitometer, comprising the steps of: (a) immobilizing cultured cells in a hydrophilic matrix; (b) placing the matrix in molten paraffin; (c) cooling the paraffin until it solidifies; and (d) without substantial intervening fixation, sectioning the solidified paraffin containing the immobilizied cells into at least one thin slice suitable for optical microscopy. The '848 patent recites essentially the same claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7, 9, 11, 13, 15, 19, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battifora (USPN 5,610,022) in view of Williamson (USPN 5,817,032).

The instant invention is drawn to a method of preparing calibration slides for cell imaging densitometer, comprising the steps of: (a) immobilizing cultured cells in a hydrophilic matrix; (b) placing the matrix in molten paraffin; (c) cooling the paraffin until it solidifies; and (d) without

substantial intervening fixation, sectioning the solidified paraffin containing the immobilizied cells into at least one thin slice suitable for optical microscopy

Battifora discloses a method of preparing calibration slides for cell imaging densitometer, see abstract. Battifora teaches immobilizing cultured cells in a gel of agar or gelatin (both hydrophilic matricies), column 1, lines 51-52. Battifora further discloses placing the matrix in paraffin, column 5, claim1. Battifora teaches intervening fixation (column 2, lines 35-36) with immobilized cells suitable for optical microscopy (column 4, lines 33-35). For the purpose of this claim and what it encompasses, the interpretation is that some intervening fixation took place. Battifora does not teach placing the sample in molten paraffin and cooling the molten paraffin until it solidifies.

Williamson discloses hot (molten) paraffin wax poured into a mold to immobilize tissue. After cooling, the wax block is removed (column 3, lines 64-66).

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to use molten paraffin wax to immobilize tissue as taught by Williamson. Although Battifora did not teach the use of molten paraffin, absent some evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have done so for simplification of the process.

Claims 1, 2, and 4-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Esteban et.al (Am.J.Clin.Pathol., 1994; 102,158-162) in view of Fisher et.al. (Br.J. Cancer, 1994; 69, 26-31)

The instant invention is drawn to a method of measuring the amount of protein of interest in a cell, wherein the tumor –associated protein is p53.

Esteban teaches the biologic significance of quantitative estrogen receptor immunohistochemical assay by image analysis in breast cancer, see entire article. Esteban does not specifically teach p53 protein in breast cancer.

Fisher teaches immunostaining for p53 in mammary carcinomas, see, i.e., for example, page 26.

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to use the immunohistochemical assay by image analysis of Esteban with the immunostaining of p53 for mammary carcinomas as taught by Fisher, because both teach assay method for the evaluation of breast cancer.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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